



**UNITED STATES DEPARTMENT OF COMMERCE
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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
08/889,017	07/07/97	SHEHADA	R P07-38135

MM61/1207

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EXAMINER

ISRAEL, A

ART UNIT

PAPER NUMBER

2878

DATE MAILED: 12/07/98

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

08/889,017

Applicant(s)

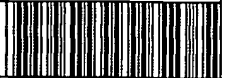
Shehada et al.

Examiner

Andrew Israel

Group Art Unit

2878



☒ Responsive to communication(s) filed on Jul 7, 1997

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-56 is/are pending in the application.

Of the above, claim(s) 43-47 is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 1-7, 11-24, 29-34, 36-39, 41, 48, 50, and 52-56 is/are rejected.

☒ Claim(s) 8-10, 25-28, 35, 40, 42, 49, and 51 is/are objected to.

☒ Claims 1-56 are subject to restriction or election requirement.

Application Papers

☒ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☒ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____.

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____.

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 1.5

☐ Interview Summary, PTO-413

☒ Notice of Draftsperson's Patent Drawing Review, PTO-948

☒ Notice of Informal Patent Application, PTO-152 (INFORMAL ABSTRACT)

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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DETAILED ACTION

Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-42 and 48-56, drawn to a spectroscopic method and apparatus for analyzing a sample by detecting return radiation at two distances, classified in class 250, subclass 458.1.
- II. Claims 43-47, drawn to a method for determining the oxygenation of a sample by comparing the wavelength of peak transmittance to the peak transmittance wavelength of a sample with known oxygenation, classified in class 600, subclass 317.

The inventions are distinct, each from the other because:

two separate and distinct methods are claimed for analyzing biological samples; the second method (group II) is not merely a different recitation of the same embodiment of the first group and therefore must be examined independent of the first group of claims.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation with Ms. Anne Wang, ESQ. on November 5, 1998 and November 17, 1998 a provisional election was made without traverse to prosecute the invention

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of group I, claims 1-42 and 48-56. Affirmation of this election must be made by applicant in replying to this Office action. Claims 43-47 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Specification

1. The abstract of the disclosure is objected to because the length exceeds the minimum of one paragraph. Correction is required. See MPEP § 608.01(b).
2. The disclosure is objected to because of the following informalities: Figures 2(a), 2(b), 2(c), 3(a), and 3(b) are not specifically or separately mentioned in the brief description of the drawings.

Appropriate correction is required.

Claim Rejections - 35 USC § 112

3. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

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4. Claims 32 and 56 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 32 recites the limitation "the biological material" in line 3. There is insufficient antecedent basis for this limitation in the claim.

Claim 33 recites the limitation "the tissue" in line 2. There is insufficient antecedent basis for this limitation in the claim.

Claim 56 recites the limitation "the first and second signals" in lines 18-19. There is insufficient antecedent basis for this limitation in the claim.

Claim Rejections - 35 USC § 102

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371© of this title before the invention thereof by the applicant for patent.

6. Claims 1, 2, 4-7, 11, 18, 30, 31, 33, 34, 39, 41, 48, 50, and 52 are rejected under 35 U.S.C. 102(b) as being anticipated by Zuckerman (U.S. Patent # 5,495,850). Concerning

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claims 1, 2, 4-7, 11, 18, 30, 31, 33, 34, 39, 41, 48, 50, and 52, Zuckerman discloses in Figure 3 and column 10, lines 1-48, a spectroscopic method and device for determining a physiological characteristic of a biological sample (or hemoglobin concentration, see col. 2, line 41), comprising: irradiating a living tissue (or biological) sample (col.8, line 17) with substantially monochromatic radiation through waveguide (or optical fiber bundle) 66 from source 52 to induce fluorescence (col. 8, lines 17-20) in the sample; monitoring a first portion of the modulated return fluorescence at a first distance from the sample with a first sensor 88A; monitoring a second portion of the return fluorescence at a second distance from the sample with a second sensor 88B; and processing the first and second portions of the return radiation with microprocessor 90 using a predictive model (see abstract). The oxygen concentration (a physiological property) of the sample is measured by this method.

7. Claims 1-7, 11-22, 30, 31, 36-38, and 53-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Alfano et al (U.S. Patent # 5,635,402). Alfano discloses in Figure 2 and column 4, lines 20-32 and column 5, lines 36-68, an apparatus and method for determining a physiological or pathological (malignancy) property of a living tissue sample (or sample volume), comprising a monochromatic laser source 43 (see col. 5, line 38 and col. 4, line 20); a first waveguide (optical fiber bundle) B disposed a first distance from a biological sample S to transmit radiation to the sample and induce fluorescence of the sample; a first sensor 59 for determining the intensity of the first portion of modulated return light; a second waveguide (optical fiber bundle) 53 disposed at a second distance for receiving a second portion of return light; a second sensor 61 for

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determining the intensity of the second portion of return light; and a processor 52 adapted to determine a physiological property of the biological material.

Claim Rejections - 35 USC § 103

8. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103© and potential 35 U.S.C. 102(f) or (g) prior art under 35 U.S.C. 103(a).

9. Claims 23 and 24 are rejected under 35 U.S.C. 103(a) as being unpatentable over Alfano et al (U.S. Patent # 5,635,402). Alfano does not disclose a method where first and second radiation signals are measured consecutively or simultaneously. However, it would have been obvious to one of ordinary skill in the art at the time of the invention to make these measurements consecutively ^{or} ~~and~~ simultaneously depending on the nature of the experiment being performed.

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10. Claims 29 and 32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zuckerman (U.S. Patent # 5,495,850) in view of Powers (U.S. Patent # 5,760,406). Zuckerman does disclose a method for determining a physiological property (oxygen concentration) of a sample. Zuckerman does not disclose a method for the measurement of the intrinsic fluorescence ^{and 32} of a sample. Regarding claims 29 ~~and 32~~, Powers discloses in Figure 1 and column 4, lines 23-65, a method and apparatus for determine the intrinsic fluorescence of a sample. It would have been obvious to one of ordinary skill in the art at the time of the invention to modify the method of Zuckerman to measure the intrinsic fluorescence of a sample in order to gain more accurate information about the physiological properties of the sample.

Allowable Subject Matter

11. Claims 8-10, 25-28, 35, 40, 42, 49, and 51 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

12. The following is a statement of reasons for the indication of allowable subject matter: claim 8, 40, and 42 are allowable because Zuckerman makes no disclosure of attenuation measurements of a sample; claim 35 is allowable because Zuckerman and Alfano do not disclose the property to be measured as being hypoxia; claim 49 is allowable because Alfano does not disclose the predictive model as being multivariate; claim 51 is allowable because Alfano does

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not disclose the predictive model as being multicriteria; and the remainder of the claims are allowable due to their dependence.

Conclusion

13. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Andrew Israel whose telephone number is (703) 305-0382.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Technology Center 2800 receptionist whose telephone number is (703) 308-0956.

Papers related to Technology Center 2800 applications **only** may be submitted to Technology Center 2800 by facsimile transmission. Any transmission not to be considered an official response must be clearly marked "DRAFT." The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 34-35 (November 15, 1988). The Fax number for Group Art Unit 2878 is (703) 308-7722 or (703) 308-7724.

AI
A.I.
November 20, 1998

Edward Westin

Edward P. Westin
Supervisory Patent Examiner
Technology Center 2800



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

Address: COMMISSIONER OF PATENTS AND TRADEMARKS
Washington, D.C. 20231

08/889,017
APPLICATION NUMBER FILING DATE FIRST NAMED APPLICANT ATTY DOCKET NO./TITLE

DATE MAILED:

NOTICE OF INFORMAL APPLICATION

(Attachment to Office Action)

This application does not conform with the rules governing applications for the reason(s) checked below. The period within which to correct these requirements and avoid abandonment is set in the accompanying Office action.

A. A new oath or declaration, identifying this application by the application number and filing date is required. The oath or declaration does not comply with 37 CFR 1.63 in that it:

1. ☐ does not identify the city and state or foreign country of residence of each inventor.
2. ☐ does not identify the citizenship of each inventor.
3. ☐ does not state whether the inventor is a sole or joint inventor.
4. ☐ does not state that the person making the oath or declaration:
 - a. ☐ has reviewed and understands the contents of the specification, including the claims, as amended by any amendment specifically referred to in the oath or declaration.
 - b. ☐ believes the named inventor or inventors to be the original and first inventor or inventors of the subject matter which is claimed and for which a patent is sought.
 - c. ☐ acknowledges the duty to disclose information which is material to the examination of the application in accordance with 37 CFR 1.56(a).
5. ☐ does not identify the foreign application for patent or inventor's certificate on which priority is claimed pursuant to 37 CFR 1.55, and any foreign application having a filing date before that of the application on which priority is claimed, by specifying the application serial number, country, day, month, and year of its filing.
6. ☐ does not state that the person making the oath or declaration acknowledges the duty to disclose material information as defined in 37 CFR 1.56(a) which occurred between the filing date of the prior application and filing date of the continuation-in-part application which discloses and claims subject matter in addition to that disclosed in the prior application (37 CFR 1.63(d)).
7. ☐ does not include the date of execution.
8. ☐ does not use permanent ink, or its equivalent in quality, as required under 37 CFR 1.52(a).
9. ☐ contains non-initialed alterations (See 37 CFR 1.52(c)).
10. ☐ Other:

B. Applicant is required to provide:

1. ☐ A statement signed by applicant giving his or her complete name. A full name must include at least one given name without abbreviation as required by 37 CFR 1.41(a).
2. ☐ Proof of authority of the legal representative under 37 CFR 1.44.
3. ☐ An abstract in compliance with 37 CFR 1.72(b).
4. ☐ A statement signed by applicant giving his or her complete post office address (37 CFR 1.33(a)).
5. ☐ A copy of the specification written, typed, or printed in permanent ink, or its equivalent in quality as required by 37 CFR 1.52(a).
6. ☒ Other:

Abstract should be on one
and a single paragraph

Page.
~~100~~